IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC. AND RAREGEN, LLC, Plaintiffs, v. UNITED THERAPEUTICS CORPORATION AND SMITHS MEDICAL ASD, INC., Defendants.	Civil Action No. 3:19-cv-10170-BRM-LHG [redacted]

DECLARATION OF CHRIS QUINN IN SUPPORT OF SMITHS MEDICAL ASD, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Chris G. Quinn, declare as follows:

1. I am the Chief Technical Engineer for the Infusion Business at Smiths Medical ("Smiths"). I have personal knowledge of the matters set forth in this declaration, and if called upon as a witness, I could and would testify competently to them.

2. I joined Smiths in 2012 as a Director, a position I held for two years. I was then promoted to Senior Director, and ultimately Chief Technical Engineer.

3. Smiths elected to discontinue the CADD-MS 3 ("MS 3") for a variety of reasons, including regulatory compliance issues. Exh. 404 at SM00018287.

4. Compliance with the Restriction of Hazardous Substances ("ROHS") regulations in EU meant Smiths needed to update several components to continue selling the MS 3 pump in the EU.

5. In addition to these regulatory issues, several components were discontinued or were likely to be discontinued. In some cases, Smiths had already secured last time buys.

6. For example, by the end of 2014, the motor used in the MS 3 pump was obsolete, and the manufacturer had issued a last-time-buy offer. The flash (microprocessor) used in the MS 3 pump had also been discontinued by the manufacturer. The flash is a critical component of the pump because it holds the memory and the instructions for use that are programmed into the pump. If replacement of the flash required redesign of the main Printed Circuit Board (PCB), the pump would need to be resubmitted for regulatory approval. Resource commitments to other projects prohibited us from dedicating the necessary time and money, and manpower on our own to redesign and resubmit the MS 3 for regulatory clearance.

7. Additionally, the molds needed to make the injection molded components for the pump and cartridges had exceeded or were approaching their anticipated useful life, making their continued use unpredictable and their manufacturing yield uncertain. Procuring more of the specific resin that Smiths had used for the MS 3 cartridge since 2005 was also a significant challenge, due to the original manufacturer discontinuing that resin in 2012.

8. By 2015, most of the MS 3 pumps and cartridges in the United States were being used by Remodulin patients. The addressable market for MS 3 pumps and cartridges in the United States, as determined by Smiths' Global Product Marketing team, did not justify additional investment into the insufficiently profitable MS 3 product line, particularly given the need to commit resources to other projects and products more aligned with Smiths' strategic priorities at that time.

9. For these and other reasons, Smiths made the decision in 2014 that it would discontinue the MS 3 pump platform.

10. Smiths reached out to the largest previous purchasers of the MS 3 pump in early 2015 to let them know about the planned discontinuation of the MS

3 pump platform. Smiths issued a formal end-of-life notice to all United States customers in August 2015. In the end-of-life notice, Smiths notified customers that it intended to provide cartridges for the pump for approximately three years. SM00028117.

11. Smiths planned to continue manufacturing pumps until it ran out of parts from its previous last-time buys. Smiths expected to stop producing pumps before the end of 2015. In fact, we ran out of production parts and shut down the line in October 2015, and we intended that shutdown to be permanent. Exh. 404 at SM00018291.

Relationship with UTC

12. When Smiths reached out to major customers in early 2015 to notify them that we were discontinuing the MS 3, and subsequently published the EOL to the general public, UTC was the only current or potential customer who expressed serious concerns that MS 3 discontinuation would impact new patients who were prescribed Remodulin subcutaneously and wanted to take action to remedy that concern.

13. At the time, Smiths was aware that UTC was pursuing the development of a new system with DEKA, but that the timing on it was uncertain.

14. Throughout 2015, and into early 2016, Smiths had several meetings and discussions with UTC about future pump supply. During those meetings, Smiths presented several options to UTC, including selling the MS 3 platform to UTC, recertifying existing pumps, and extending the life of the platform. Exh. 404 at SM00018289.

15. Smiths was already overcommitted in its business because it had decided to reengineer multiple pump platforms to comply with new IEC 60601-2-24, 2012 requirements, so we could not afford to extend the life of the MS 3

platform by ourselves. Smiths received a bid from an outside design service firm to re-engineer the MS 3 pump platform to be compliant with the IEC 60601 standard. The bid was between [redacted] for 12-18 months of work. Exh. 402 at SM00017526.

16. I was involved in many of the relevant discussions in 2015 and 2016 with UTC and participated in the internal work to determine what would be necessary to put the MS 3 pump back into production.

17. UTC needed to make a financial commitment to Smiths to provide the necessary economic incentive for Smiths to resurrect the pump and source additional resin for the cartridges. UTC made it clear to us that in exchange for such a financial commitment, UTC needed Smiths to agree to exclusivity on any MS 3 extension in order to ensure access to supplies by Remodulin patients.

18. We ultimately agreed that Smiths would produce [redacted] MS 3 pumps and [redacted] MS 3 cartridges to bridge the expected supply gap between discontinuance of the MS 3 and the release of UTC's next generation subcutaneous delivery system, for sale by Smiths to certain customers for use with Remodulin. Smiths stopped manufacturing pumps in 2017 and sold the remainder to UTC. Smiths no longer manufactures or sells MS 3 pumps.

19. The commitment by UTC to make an upfront payment of [redacted] and to purchase a given amount of cartridges and any pumps that did not sell to the specified customers allowed Smiths to lock in volume commitments from key suppliers thereby reducing costs and guaranteeing supply continuity.

20. Without this large up-front financial commitment and the guaranteed purchase commitment from UTC, Smiths would not have put the pumps back into production, nor would it have pursued additional production of cartridges. After all, we had already determined that it did not make financial sense to keep producing pumps and had shut the manufacturing line down.

21. UTC's commitment, including the [redacted] advance payment, provided the necessary financial incentive for Smiths to complete the necessary fixes and to extend production of both the MS 3 pumps and cartridges.

Cartridges/Resin

22. Smiths understood the overarching purpose of the Supply Agreement with UTC was to ensure that patients could continue to subcutaneously infuse Remodulin using both the pumps and the cartridges that Smiths committed to supply—because the pumps are unusable without the cartridges.

23. Calculating how much resin is needed to make MS 3 cartridges is not an exact science. As molds age, they can become less efficient, wasting more resin and changing yield unpredictably. Therefore, the number of MS 3 cartridges you can produce from a given supply of resin is not exact and varies over time.

24. When Smiths prepared to discontinue the MS 3 in 2014, it made a last time buy of the specific resin it had used to produce MS 3 cartridges since 2005. The original manufacturer had stopped making the resin in 2012, so Smiths had to find an alternate source for that particular resin that would not require extensive testing and verification.

25. In 2016, Smiths did locate a company that had the resin we needed and purchased additional resin to meet its commitment to UTC.

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I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 24th day of October 2019, in CEDAR RAPIDS, IOWA.

Chris Dunn